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| PPLICATION NO.                              | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.    | CONFIRMATION NO |
|---|-------------|----------------------|------------------------|-----------------|
| 10/020,331                                  | 12/12/2001  | Michael T. Milbocker | PRAXIS-5               | 9980            |
| 7590 12/30/2003                             |             | EXAMINER             |                        |                 |
| PROMETHEAN SURGICAL DYNAMICS LLC 3 GILL ST. |             |                      | DI NOLA BARON, LILIANA |                 |
| SUITE G                                     |             | •                    | ART UNIT               | PAPER NUMBER    |
| WOBURN, MA 01810                            |             |                      | 1615                   |                 |

DATE MAILED: 12/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| 4   | Application No.           | Applicant(s)                                    |  |  |  |  |
|---|---------------------------|---|--|--|--|--|
| Office Action Summary   | 10/020,331                | MILBOCKER, MICHAEL T.                           |  |  |  |  |
| Office Action Summary   | Examiner                  | Art Unit  |  |  |  |  |
| The BERLING DATE: 4.11  | Liliana Di Nola-Baron     | 1615  |  |  |  |  |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply  |                           |   |  |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).   |                           |   |  |  |  |  |
| 1)⊠ Responsive to communication(s) filed on <u>16 October 2003</u> .  |                           |   |  |  |  |  |
| 2a)☐ This action is <b>FINAL</b> . 2b)⊠ This a  | ction is non-final.       |   |  |  |  |  |
| 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.  |                           |   |  |  |  |  |
| Disposition of Claims   |                           |   |  |  |  |  |
| 4) ☐ Claim(s) 1-39 is/are pending in the application. 4a) Of the above claim(s) 31-39 is/are withdrawn from consideration.  5) ☐ Claim(s) is/are allowed.  6) ☐ Claim(s) 1-30 is/are rejected.  7) ☐ Claim(s) is/are objected to.  8) ☐ Claim(s) are subject to restriction and/or election requirement.  |                           |   |  |  |  |  |
| Application Papers  |                           |   |  |  |  |  |
| 9)☐ The specification is objected to by the Examiner.   |                           |   |  |  |  |  |
| 10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner.   |                           |   |  |  |  |  |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).   |                           |   |  |  |  |  |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  |                           |   |  |  |  |  |
| 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.  |                           |   |  |  |  |  |
| Priority under 35 U.S.C. §§ 119 and 120   |                           |   |  |  |  |  |
| <ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> <li>13) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet.</li> <li>37 CFR 1.78.</li> <li>a) The translation of the foreign language provisional application has been received.</li> <li>14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.</li> </ul> |                           |   |  |  |  |  |
| Attachment(s)   |                           |   |  |  |  |  |
| Notice of References Cited (PTO-892)     Notice of Draftsperson's Patent Drawing Review (PTO-948)     Information Disclosure Statement(s) (PTO-1449) Paper No(s)  | 5) Notice of Informal Pat | PTO-413) Paper No(s) tent Application (PTO-152) |  |  |  |  |

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## DETAILED ACTION

## Election/Restrictions

1. Applicant's election with traverse of Group I, claims 1-30, is acknowledged. The traversal is on the ground(s) that the claims are directed to a composition and a method of use of the composition. This is not found persuasive because the process of using the product as claimed in Group II, namely tissue bonding, can be achieved using compositions other than Applicant's claimed composition, such as polyurethane polymers, which have adhesive properties, and the compositions claimed in Group I may be used as polymeric foams.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 31-39 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Claims 1-30 will be examined in this Office action.

## Claim Rejections - 35 USC § 103

- 3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 4. Claims 1-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Muller et al. (U.S. Patent 5,624,972).

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The patent provides polymeric compositions comprising isocyanate-terminated polymers and a polyisocyanate composition (See col. 3, lines 8-16).

With regard to claims 1 and 2, the patent teaches that the composition is obtained by reacting an isocyanate-reactive polymer having functionality between 2 and 8 with an excess of isocyanate composition (See col. 3, lines 8-16). Additionally, the patent teaches that the composition comprises at least one other free polyisocyanate composition (See col. 6, lines 38-62). The patent does not specifically teach that the composition comprises (N-1)% of free polyisocyanate, however, one of ordinary skill would have been able to determine the optimal concentration of free isocyanate by routine experimentation.

Regarding claims 3-5, the patent indicates that copolymers of ethylene and propylene oxides are particularly useful polyols, as well as mixtures of polypropylene-polyethylene oxide polyols with a different polyol (See col. 4, line 63 to col. 5, line 11). The patent does not specifically teach the content of polypropylene oxide in the polyols of the invention, however, one of ordinary skill in the art would have been capable of determining the optimal content of polypropylene oxide by routine experimentation.

With respect to claims 6, 7 and 9, the patent includes the 80:20 mixture of 2,4-toluene diisocyanate and 2,6-toluene diisocyanate among the preferred free toluene diisocyanate compositions for use in the invention (See col. 4, lines 14-19).

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Regarding claims 8 and 10, the patent includes isophorone diisocyanate in the diphenylmethane diisocyanate composition used to cap the polymer (See col. 3, lines 57-65) and in the free polyisocyanate composition (See col. 6, lines 38-49).

With respect to claims 11-14, the patent includes aliphatic diisocyanates among the polycyanates used to endcap the polyol (See col. 3, lines 57-65) and aromatic polyisocyanates in the free polyisocyanate composition (See col. 6, lines 38-62). The patent is silent with regard to the features of the isocyanates claimed by Applicant, such as the rate of conversion to amine, reactivity with nitrogen substances and viscosity. The burden is shifted to Applicant to show that the aliphatic and aromatic isocyanates disclosed by the prior art would not be capable of showing the same features as those claimed by Applicant.

Regarding claims 15-22, the patent teaches that mixtures of polypropylene-polyethylene oxide polyols with a different polyol are particularly useful in the compositions of the invention (See col. 5, line 8 to col. 6, line 20). The patent does not disclose the functionality of the various polyols contemplated in the compositions of the invention, however, the prior art provides the general teachings that the isocyanate-reactive polymer has an average functionality of 2 to 8, and teaches that mixtures of two or more isocyanate-reactive polymers varying in functionality, weight and/or chemical constitution may be used (See col. 4, lines 20-41). The patent does not specifically teach the content of polypropylene oxide in the polyols of the invention, however, one of ordinary skill in the art would have been capable of determining the optimal content of polypropylene oxide by routine experimentation.

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With regard to claims 23-25, the patent includes aliphatic and aromatic polyisocyanates as suitable compositions for reacting the polymer (See col. 3, lines 54-65).

With respect to claims 26 and 27, the patent includes the 80:20 mixture of 2,4-toluene diisocyanate and 2,6-toluene diisocyanate among the preferred free toluene diisocyanate compositions for use in the invention (See col. 4, lines 14-19).

With regard to claims 28-30, the patent is silent with respect to the elimination of amines from the composition during polymerization, however, the patent contemplates addition of water to react with the composition of the invention and produce a foam (See col. 8, lines 54-65) and includes isophorone diisocyanate among the polyisocyanates used to endcap the polymer (See col. 3, lines 54-65). The patent does not specifically teach the content of polypropylene oxide in the polyols of the invention, however, one of ordinary skill in the art would have been capable of determining the optimal content of polypropylene oxide by routine experimentation. The burden is shifted on Applicant to show that the compositions disclosed by the prior art would have not been capable of eliminating amines, as claimed by Applicant.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to apply the teachings of Muller et al. to device compositions comprising one or more polyols terminated with a polyisocyanate and free polyisocyanate. The expected result would have been a successful flexible polyisocyanate polymeric composition. Because of the teachings of Muller et al., that flexible, moldable compositions may be obtained by

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combining polyisocyanate-terminated polyols with free polyisocyanate, one of ordinary skill in

the art would have a reasonable expectation that the compositions claimed in the instant

application would be successful. Therefore the invention as a whole would have been prima

facie obvious to one of ordinary skill in the art at the time the invention was made.

Any inquiry concerning this communication or earlier communications from the

examiner should be directed to Liliana Di Nola-Baron whose telephone number is 703-308-

8318. The examiner can normally be reached on Monday through Thursday, 5:30AM-4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Thurman K Page can be reached on 703-308-2927. The fax phone number for the

organization where this application or proceeding is assigned is 703-305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding

should be directed to the receptionist whose telephone number is 308-1234/1235.

December 21, 2003